

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and  
RONALD LEWIS

*Plaintiffs,*

v.

ALEX AZAR,

*Defendant.*

Case No. 2:20-cv-00738-CMR

**PLAINTIFFS' REPLY IN FURTHER SUPPORT OF MOTION  
FOR SUMMARY JUDGMENT AND OPPOSITION  
TO CROSS-MOTION FOR SUMMARY JUDGMENT**

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The Secretary's opposition and cross-motion<sup>1</sup> brings to mind a story by famed attorney and judge, Irving Younger:

A farmer has a patch of cabbages, his neighbor has a goat. One day, the goat breaks through the fence and eats the cabbages. The farmer brings suit for damages. The neighbor replies:

You had no cabbages.  
If you had any cabbages, they were not eaten.  
If your cabbages were eaten, it was not by a goat.  
If your cabbages were eaten by a goat, it was not my goat.  
And if it was my goat, he was insane!

The Secretary's opposition employs the same approach:

Collateral estoppel against the government is unconstitutional.  
If it is constitutional, the Supreme Court has said it can't be done.  
If the Supreme Court has not said it can't be done, then they have never done it.  
If they have done it, then the right papers are not in the file.  
Etc. (for 33 pages).

The Secretary's cross-motion should be denied. Mrs. Oxenberg and Mr. Lewis' motion should be granted and coverage ordered.

## **I. DISCUSSION**

The bulk of the Secretary's opposition is founded on conflating mutual and non-mutual collateral estoppel, "precedential" and "collateral estoppel", "equitable estoppel" and "collateral estoppel", etc. Thus, the Secretary freely mixes quotes from cases discussing each (as if there were no difference) wherever the quoted language sounds good. Obviously, that approach is without merit. In addition, the Secretary's opposition relies on a series of factual assertions that simply are not true. Further, nearly all of the legal arguments offered by the Secretary in this case were contradicted in a brief filed by the Secretary in another case one day later.

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<sup>1</sup> Because the Secretary filed a combined 33-page opposition and cross-motion, Plaintiffs are abiding by this Court's page limit requirements applicable to opposition briefs.



Along these same lines, the Secretary's cross-motion seeks to have the entire case dismissed if the Court declines to apply collateral estoppel and declines Plaintiffs' motion. The cross-motion reflects a fundamental misunderstanding of the procedural posture of this case and the basis for Plaintiffs' motion for summary judgment. Plaintiffs moved to apply collateral estoppel to be spared relitigating the same coverage issues that they had already won, but if denied, Plaintiffs have not waived their other grounds for relief and, thus, remain entitled to prove their case on the merits once again.

The majority of the Secretary's opposition and cross-motion is directed to something other than refuting Mrs. Oxenberg' and Mr. Lewis' showing with regard to the elements of collateral estoppel. In the interest of clarity, the areas of disagreement regarding the elements of collateral estoppel are addressed before turning to the bulk of the Secretary's brief.

#### **A. Reply on Mrs. Oxenberg' and Mr. Lewis' Motion for Summary Judgment**

With regard to the elements of collateral estoppel, as far as Plaintiffs can tell, the Secretary's disputes first appear on pages 24-27 of his opposition.

First, the Secretary contends that because each of the relevant decisions relates to claims for coverage of certain months, the issues litigated and determined in the decisions are different. Opp. at 24-25. That proposition should be rejected outright. As this Court recognized in *DVI Receivables XIV, LLC. v. National Medical Imaging, LLC.*, 529 B.R. 607, 622 (E.D.P.A. 2015) (Rufe, J), whether facts or issues are identical for collateral estoppel purposes is measured by materiality. Here, there is no material difference, for example, as to whether TTFT is "medically reasonable and necessary"/"safe and effective" (and a Medicare covered benefit) for Mrs.

Oxenberg when decided for a claim arising in July 2018 or for a claim arising in June 2018.<sup>2</sup> The same facts/issues were actually litigated and determined in the final favorable decisions on which collateral estoppel is based and are at issue in the adverse decisions appealed in this case.

Second, the Secretary asserts that different issues were decided because, even though all the decisions addressed and resolved whether TTFT was “medically reasonable and necessary” (and a covered Medicare benefit) for Mrs. Oxenberg and Mr. Lewis, the decisions appealed in this case used different rationales to support their opposite conclusions. Opp. at 25. Again, that is wrong as a matter of law. The determinative issue presented and decided was the same in all of Plaintiffs’ TTFT claims (*i.e.*, whether TTFT was “medically reasonable and necessary”/a covered Medicare benefit). Precluding the losing party from using some new or different justification to arrive at an inconsistent conclusion on the identical issue is the very purpose of the collateral estoppel doctrine. *See, e.g., Allen v. McCurry*, 449 U.S. 90, 94 (1980) (“[R]es judicata and collateral estoppel relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by preventing inconsistent decisions, encourage reliance on adjudication.”).

The Secretary’s final argument that he did not have a full and fair opportunity to litigate the issues before ALJs of his own department (Opp. at 26-27) is addressed below. In short, Mrs. Oxenberg’ and Mr. Lewis’ showing was not rebutted and summary judgment in their favor should be granted.

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<sup>2</sup> The Secretary’s reliance on *Applied Medical Resources Corp. v. United States Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (Opp. at 25) is particularly off-base. *Applied* is a patent case discussing reasonable royalties. Under Federal Circuit precedent, a reasonable royalty is based on the rate the parties would have accepted in a hypothetical negotiation taking place just before the infringement began. Thus, the reasonable royalty determined in one case for infringement beginning on one date cannot collaterally estop either party from arguing for a different reasonable royalty for separate acts of infringement beginning on a different date at issue in a later case.

**B. Correction of Errors/Incomplete Statements of Fact**

Before addressing any of the Secretary's legal arguments, correction of four errors/incomplete statements of fact may clarify consideration of the issues.

**1. The Secretary's Comments about the Record/Council Review**

The Secretary alleges that the decision on which collateral estoppel is based in Mr. Lewis' case (ALJ Appeal No. 3-8693279102) should be excluded because it is not part of the Administrative Record. Opp. at 11. That is difficult to follow because the Record served by the Secretary on April 20, 2020, includes that decision at CAR 731-739. Likewise, the Secretary asserts that some or all of the decisions on which collateral estoppel is based in Mrs. Oxenberg's case (ALJ Appeal Nos. 1-8452468241, 1-8651098761, and 3-8686737644) should be excluded because they are not part of the Record. Opp. at 11. Again, the Record served by the Secretary includes those decisions at CAR 6-47. Thus, as a factual matter, the Secretary's assertion that the favorable decisions giving rise to collateral estoppel are not part of the Record for each Plaintiff is false.

The Secretary also asserts that: "Plaintiffs filed the instant action instead of seeking a hearing before the Council." Opp. at 9. Again, that is false. As shown at CAR 52-56 (for Mrs. Oxenberg) and CAR 741-45 (for Mr. Lewis), each Plaintiff sought such a hearing. However, in both instances, the Council failed to act within the 90-day time period mandated by Congress (*see* 42 U.S.C. § 1395ff(d)(2)(A)) and this suit was properly filed.

**2. The Secretary's "Future Claims" and Revised LCD Comments**

The Secretary makes several mischaracterizations that Mrs. Oxenberg and Mr. Lewis are seeking to recover for "future claims" in this case and the possible effect, if any, of the revised LCD that went into effect on September 1, 2019. Opp. at 2, 3, 6-7, 31-32. Such comments misapprehend the basis of this case and the relief sought.

At issue in this case is Mrs. Oxenberg's claim for coverage for the months of April-June 2018 and Mr. Lewis' claim for coverage for the months of July-October 2018. No other claims are at issue and no prospective relief is sought. Thus, the Secretary's long quote from *Almy v. Sebelius*, 679 F.3d 297, 311 (4th Cir. 2012) and citations to *Porzecanski v. Azar*, 943 F.3d 472, 483 (D.C. Cir. 2019) (claim for "future benefits") simply miss the mark. When Mrs. Oxenberg and/or Mr. Lewis submit additional claims in the future for TTFT coverage, any decision as to whether collateral estoppel will apply to those claims will depend on the facts and issues relevant at the time.

As set forth in the Complaint, a case like this technically seeks "injunctive relief" not "damages" (*i.e.*, an injunction requiring the Secretary to provide coverage for the claims at issue). *See Bowen v. Massachusetts*, 487 U.S. 879, 893-901 (1988). Thus, the Secretary misunderstands the nature of the injunction sought. Accordingly, the Secretary's comments regarding "future claims", "presentment" (*i.e.*, the requirement to submit a claim), "channeling" (*i.e.*, the requirement to proceed through the claim process) (Opp. at 2, 20-22), and the revised LCD that took effect after the claims at issue in this case are simply irrelevant.

### **3. The Secretary's Comments Regarding Pending ALJ Appeals**

Citing non-Record information from 2014, the Secretary claims that "over 400,000 Medicare claim appeals ... are filed each year at the ALJ level." Opp. at 2-3. That is false.

This is not the only litigation that the Secretary is involved in. One of the other cases is *American Hospital Association v. Sebelius*, Case No. 14-cv-851-JEB, (D.D.C.). There, the Court issued a *writ of mandamus* ordering the Secretary to reduce the backlog of cases pending before ALJs according to a schedule and to provide status reports of the Secretary's progress to the Court. On March 25, 2020, (*i.e.*, less than a month before the Secretary filed his opposition/cross-motion in this case), the Secretary filed his latest status report in the D.C. case.

Rather than the “over 400,000 Medicare claim appeals ... filed each year at the ALJ level”, the status report provided to the D.C. Court for FY 19 indicates that 43,887 appeals were filed at the ALJ level. *See Pistorino Dec. Ex. I.*<sup>3</sup> That is, the true number is ~11% of what was represented to this Court. In Plaintiffs’ view, even ~44,000 appeals substantially overstates the relevant figure because it includes appeals of all kinds, the vast majority of which are hospital/provider appeals.

This is a “beneficiary appeal”, *i.e.*, an appeal by Mrs. Oxenberg and Mr. Lewis themselves as opposed to an appeal by a hospital/provider that is likely to have much more substantial resources than Mrs. Oxenberg and Mr. Lewis and for whom delay is less of a burden. The Secretary has published data for FY 19 indicating that 5,148 beneficiary appeals were filed at the ALJ level, *i.e.*, ~1.3% of the represented 400,000 figure.<sup>4</sup> Indeed, that figure is overstated because it includes appeals in Social Security cases.

Even a figure limited to Medicare beneficiary appeals would likely overstate the true number. Though the Secretary has published no data, it is believed that the vast majority of Medicare beneficiary appeals are by unrepresented beneficiaries (*i.e.*, with no lawyer present).<sup>5</sup> By contrast, as detailed below, this case concerns appeals by represented beneficiaries - where it is indisputable that the Secretary has the full panoply of litigation rights.

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<sup>3</sup> As shown in Exhibit I to the Pistorino Declaration, the number of appeals filed at the ALJ level has fallen dramatically, every year for the last five years. In 2013 and 2014, the Secretary conducted very aggressive audits of hospital charges for in-patient care and retroactively denied hundreds of thousands of claims, which were appealed (referred to in the materials as “RAC” appeals). This spike appears to be the reason that the Secretary choose to offer data from a period 5-6 years ago rather than data that is readily available to the Secretary showing appeals filed through the end of March 2020.

<sup>4</sup> <https://www.hhs.gov/about/agencies/omha/about/current-workload/beneficiary-appeals-data/index.html> (visited April 24, 2020).

<sup>5</sup> Whether collateral estoppel can or should apply in those cases is a matter for another day.

The Court will have to decide whether it is material that the true number is 11%, 1.3%, or an even smaller figure than was represented in the Secretary's opposition - but the Court should at least have accurate information.

#### **4. The Secretary's Comments Regarding LCDs**

While Plaintiffs do not believe it to be relevant to the issues before the Court on this motion, the Secretary's comments regarding the promulgation and maintenance of LCDs generally, and the LCD discussed in the decisions below, are, at best, incomplete. Opp. at 5-7.<sup>6</sup>

It is true that LCDs are supposed to be developed by considering medical literature, etc. and be reviewed to ensure that they do not become outdated. However, the Secretary's paper does not mention that this did not happen in the case of TTFT. That is, the LCD that became effective on October 1, 2015 did not consider the suspension of the clinical trial in 2014 on the grounds that withholding TTFT from the control group would have been unethical. Likewise, the LCD was not reviewed after its issuance and did not consider the large number of scientific studies showing the effectiveness of TTFT, additional FDA approval in October 2015, the fact that TTFT had become the standard of care for GBM no later than 2018, as well as clinical trials and seminal papers concerning the same.

Because of this complete failure of process, in May 2019, ALJ Scott Anderson determined that the 2015 LCD concerning TTFT was not supported by substantial evidence. *See* Pistorino Dec. Ex. L. Thereafter, the MAC submitted a revised LCD (that is also being challenged) that only applies to dates of service after September 1, 2019. As a result, the original LCD is deemed invalid. *See* 42 C.F.R. §§ 426.420(b); 426.460(b). Accordingly, the LCD that was used to deny

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<sup>6</sup> The Secretary's citation to various sections of the Medicare Program Integrity Manual (MPIM) is also in error. The sections cited by the Secretary were adopted in 2019 while the LCD relevant to the present claims was adopted in 2015.

coverage of both Mrs. Oxenberg and Mr. Lewis' claim has been invalidated. This is a separate reason why the decisions at issue denying coverage should be reversed on the merits. Nevertheless, a proper application of collateral estoppel will prevent Mrs. Oxenberg, Mr. Lewis, and this Court from having to bear the burden of litigating the same issues again and again.

### **C. Standard of Review**

The Secretary's statement of the standard of review is erroneous. As posited by the Secretary, "a court must uphold an ALJ's findings if they are supported by substantial evidence." Opp. at 10 (citing *McGinnis v. Social Security Admin.*, 2020 WL 1623703 at \* 2 (3d Cir. April 2, 2020) and *Rutherford v. Barnhardt*, 399 F.3d 546, 552 (3d Cir. 2005)). That is not the law.

Pursuant to 42 U.S.C. § 405(g) (as amended by 42 U.S.C. § 1395ff(b)(1)(A)), "the findings of [the Secretary] *as to any fact*, if supported by substantial evidence, shall be conclusive." (emphasis added). Thus, it is only factual conclusions that are subject to the substantial evidence standard which was the focus of the holdings in the *McGinnis* and *Rutherford* cases. For all other issues, the decisions are reviewed using any standard applicable under the Administrative Procedure Act (APA). *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) (applying arbitrary and capricious standard).

In this case, Mrs. Oxenberg and Mr. Lewis have brought challenges under the various provisions of the APA (including, but not limited to, the finding not being supported by substantial evidence). *See* Complaint, Counts I-VI.

### **D. The Secretary's Legal Arguments Independent of Medicare Regarding Collateral Estoppel**

The Secretary makes a number of legal assertions about collateral estoppel that are wholly independent of the Medicare Act or Medicare claims processing. The Secretary failed to provide a Table of Contents and the various arguments are spread throughout the Secretary's brief.

Accordingly, in the interests of clarity, Plaintiffs gather their responses in this section though, to some degree, the Secretary's arguments overlap.

**1. The Secretary's Simultaneous But Inconsistent Positions Regarding Collateral Estoppel in Medicare Cases**

Before even addressing the Secretary's legal arguments, Plaintiffs note that the Secretary is simultaneously asserting diametrically opposed positions with regard to collateral estoppel before two different district courts. As noted above, this is not the only case the Secretary is involved in and, again, the Secretary's position in the other litigation does not match his position in this case.

One such case is *Lewis, et al. v. Azar*, Case No. 18-cv-2929-RBW (D.D.C.) (pending). There, lead plaintiff Carol Lewis litigated the issue of whether certain diabetes supplies (continuous glucose monitors) were covered Medicare benefits and obtained a final judgment from a district court finding that they were. *See Lewis v. Azar*, 308 F.Supp.3d 573 (D. Mass. 2018). When the Secretary continued to deny Ms. Lewis' claims on the same grounds rejected by the district court, Ms. Lewis brought another suit on behalf of herself and all others similarly situated. Because of her position as a class representative, Ms. Lewis did not assert collateral estoppel based on her prior case.

However, in opposing class certification, the Secretary asserted that the Court should *sua sponte* impose offensive collateral estoppel against the Secretary in an effort to remove Ms. Lewis as a class representative. *See Pistorino Dec. Ex. J* at 7-12. In doing so, the Secretary essentially contradicted every one of his arguments made in this case - in a brief filed one day after the Secretary's opposition/cross-motion was filed in this Court. Contrary to the arguments in this case, the Secretary argued there (either explicitly or by implication) that offensive collateral estoppel can apply against the Secretary, that the effect of prior decisions is not limited to the particular



months at issue, that there is no Constitutional bar to using collateral estoppel to order the Secretary to provide Medicare coverage, and that reliance on non-Record materials in support of collateral estoppel is appropriate.

In Plaintiffs' view, it is improper for the Secretary to assert mutually exclusive legal positions in different case in hopes of obtaining an advantage without anyone noticing.

## 2. The Supreme Court Has Affirmed the Use of Offensive Collateral Estoppel Against the United States

Page 1 of the Secretary's brief starts with the incorrect claim that: "the Supreme Court has never upheld an assertion of offensive collateral estoppel against the United States." Opp. at 1 (citing *U.S. v. Mendoza*, 464 U.S. 154 (1984)).<sup>7</sup> Opp. at 28 (same). The very case cited by the Secretary approvingly cites to a case where the Supreme Court did just that. *Mendoza* explicitly states:

The concerns underlying our disapproval of collateral estoppel against the government are for the most part inapplicable where mutuality is present, as in *Stauffer Chemical, Montana*, and *Moser*.

*Id.* at 163-64. Because it directly concerns the issue of offensive mutual collateral estoppel against the United States, the *Moser* case cited by the Supreme Court is discussed in detail below.

As recounted by the Court in *U.S. v. Moser*, 266 U.S. 236 (1924), Jefferson Moser was a Captain in the Navy. Pursuant to a statute passed by Congress, any officer who served during the Civil War was entitled to the rank and three quarters of the sea pay of the rank above him upon retirement. Mr. Moser was in the Naval Academy during the Civil War and contended that that constituted service "during the civil war." Therefore, at retirement with the rank of Captain, Mr.

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<sup>7</sup> *Mendoza* announced the Supreme Court's view that non-mutual, collateral estoppel could not be applied against the United States, while affirming that mutual collateral estoppel could be applied against the government. See, e.g., *U.S. v. Stauffer Chemical Co.*, 464 U.S. 165 (1984); *Montana v. U.S.*, 440 U.S. 147 (1979).

Moser sought the rank and three-fourths the sea pay of a Rear Admiral. When Mr. Moser's claim to the higher pay was refused, he brought suit in the Court of Claims and was victorious.

Apparently, the pay was provided in installments and Mr. Moser was forced to bring three more suits to recover subsequent installments. Each time, he was victorious. *Id.* at 66 (“Three previous suits for installments of the salary ...”). However, in the second, third, and fourth suits, the Court of Claims also rested its decision in Mr. Moser's favor on the collateral estoppel branch of the doctrine of res judicata.<sup>8</sup> *Id.* at 240 (“In the second and third Moser Cases, however, the Court of Claims declined to follow the Jasper case, holding that by reason of its decision in the first Moser Case, the question was res judicata. The present suit was decided in Moser's favor upon the same ground[.]”).<sup>9</sup> When the United States appealed the fourth decision in Mr. Moser's favor to the Supreme Court, the Supreme Court affirmed based on the application of collateral estoppel. *Id.* at 241 (“[T]he court was clearly right in its application of the doctrine of res judicata”); 242 (“[T]he point at issue is to be determined by applying the second branch of the rule. The question expressly and definitely presented in this suit is the same as that definitely and actually adjudged in in favor of the claimant in the three preceding suits[.]”). Thus, the application of offensive, mutual collateral estoppel precluded the United States from contesting that Moser's time at the Naval Academy constituted “service during the civil war” and, therefore, from denying Mr. Moser's subsequent claim.

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<sup>8</sup> “Res judicata” is a legal doctrine incorporating the concepts of “claim preclusion” (formerly known as “merger” and “bar”) and “issue preclusion” (formerly known as “collateral estoppel”). The confusing use of these terms has led to modern efforts to limit “res judicata” to mean “claim preclusion” and to use the term “issue preclusion” instead of “collateral estoppel.” See THE RESTATEMENT (SECOND) OF JUDGMENTS (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984). As used in *Moser*, the Supreme Court was using “res judicata” in its “issue preclusion” sense. See *Burlington Northern*, 63 F.3d at 1234.

<sup>9</sup> In the *Jasper* case referred to, the Court of Claims had later reached the opposite legal conclusion as to a different claimant, before changing its mind again in the next *Moser* case. *Id.* at 240.

While decided in 1924, the Supreme Court approvingly cited *Moser* in *Mendoza* and *Stauffer* (both in 1984) and the case has been cited nearly 250 times since it was decided, including by the Third Circuit. *See, e.g., Burlington N. R.R. Co. v. Hyundai N. R.R. Co., Ltd.*, 63 F.3d 1227, 1234 (3d Cir. 1995) (discussing *Moser* - “The government appealed and the Supreme Court affirmed the application of issue preclusion.”).

Thus, this Court should reject the Secretary’s fundamental assertion that offensive collateral estoppel cannot be applied against the government by a party to a prior litigation who prevails on the same issue against the government. *See also, e.g., Hanover Bank v. U.S.*, 285 F.2d 455, 459-60 (Ct. Cl. 1961) (action for refund of taxes, government estopped from recalculating taxes based on finding in prior litigation between the parties, cited in *U.S. v. Utah Construction Co.*, 384 U.S. 394, 422 (1966)).

### **3. The Secretary’s Confusion Regarding Mutual and Non-Mutual Collateral Estoppel**

On pages 27-30, the Secretary makes a number of other assertions regarding the holdings of *Mendoza*, *Parklane*, and other cases. In so doing, the Secretary confuses mutual and non-mutual collateral estoppel and the policies behind the distinction between them.

By way of background, mutual collateral estoppel (whether defensive or offensive) is a venerable aspect of Anglo-American common law. *See, e.g., Cromwell v. County of Sac*, 94 U.S. 351, 353 (1876) (citing *Outram v. Morewood*, 3 East, 346 (UK 1803), a leading English case applying offensive collateral estoppel); *Keokuk & W.R. Co. v. State of Missouri*, 152 U.S. 301, 317 (1894) (“The operation of an estoppel must be mutual.”).<sup>10</sup> Collateral estoppel serves the triple

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<sup>10</sup> *See* M. BIGELOW, “A TREATISE ON THE LAW OF ESTOPPEL OR OF INCONTESTABLE RIGHTS”, Chap. 2, § 2 (6<sup>th</sup> ed. 1913) for a detailed discussion of what would now be called “issue preclusion”/“collateral estoppel.” *Id.* at 103-4 (discussion of *Outram*). *See* Pistorino Dec. Ex. K.

purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen*, 449 U.S. at 94; *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

Mutuality was a requirement of collateral estoppel until 1971 when the Supreme Court relaxed the requirement, at least defensively, in *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971). Thereafter, in 1978 in *Parklane*, the Supreme Court further relaxed the mutuality requirement to allow non-mutual, offensive collateral estoppel (subject to various considerations). By its own terms, *Parklane* only addressed non-mutual, offensive collateral estoppel and did not purport to change the law with respect to mutual, offensive collateral estoppel. *Parklane*, 439 U.S. at 326 (“Specifically, we must determine whether a litigant who was *not a party* to a prior judgment may nevertheless use that judgment ‘offensively’ to prevent a defendant from relitigating issues resolved in the earlier proceeding.”) (emphasis added); *Id.* at 326 n. 4 (defining “offensive” and “defensive” collateral estoppel as used in the opinion); *see also Burlington*, 63 F.3d at 1232 (“[I]s referred to as offensive, non-mutual collateral estoppel, which has been recognized as proper by the Supreme Court in [*Parklane*].”).

Finally, in *Mendoza*, the Supreme Court addressed whether the more liberal collateral estoppel approach of *Blonder-Tongue* and *Parklane* applied against the United States. In *Mendoza*, the Supreme Court held that it did not because of the United States’ unique position as a litigant. In so doing, as detailed above, the Supreme Court approvingly cited cases holding that mutual collateral estoppel (even offensive) could be applied against the United States by the party to the prior, successful litigation.

With that background, the Secretary's various assertions are addressed. The Secretary's citations to *Heckler v. Community Health Services of Crawford County*, 467 U.S. 51 (1984) (Opp. at 1 and 28) are particularly inapt. *Heckler* concerns "equitable estoppel", which is an entirely different form of estoppel than is at issue in this case and has no bearing here.

The Secretary's description of *Mendoza* as "the seminal case on point" (Opp. at 28) is also misplaced because, as detailed above, that case concerns only whether non-mutual collateral estoppel can be applied against the United States (whether offensive or defensive). By contrast, the present case involves mutual collateral estoppel as it has been applied for at least 100 years against the United States.

On pages 28 and 29, the Secretary simply recounts the various policy reasons why the Supreme Court refused to extend non-mutual collateral estoppel to the United States before improperly conflating mutual and non-mutual collateral estoppel. As described by the Supreme Court itself, those concerns "are for the most part inapplicable where mutuality is present." *See Mendoza*, 464 U.S. at 163-64. Thus, when resolving claims for TTFT coverage brought by different Medicare beneficiaries, *i.e.*, cases not involving Mrs. Oxenberg or Mr. Lewis as claimants, the Secretary would still be free to make whatever decision was warranted under the facts and circumstances of those claims (*i.e.*, cases could still "percolate"). What the Secretary is not free to do is force Mrs. Oxenberg, Mr. Lewis, and the Courts to bear the burden of repeatedly litigating the identical issue in every TTFT claim brought by them, and to suffer the risk and consequence of inexplicably conflicting results.

#### **4. The Secretary's Erroneous Comments Regarding "Precedential" Decisions and Collateral Estoppel**

Respectfully, it is difficult to follow the Secretary's arguments regarding "precedential" decisions and collateral estoppel. Opp. at 13-15. Apparently, in the Secretary's view, decisions

that are “precedential” and those giving rise to “collateral estoppel” are synonymous. This reflects a fundamental misunderstanding of the distinct legal concepts at issue.

A “precedential” decision is binding on all lower courts and decision makers, regardless of the parties before them. *See, e.g., Allegheny Gen. Hosp. v. Nat’l Labor Relations Bd.*, 608 F.2d 965, 969-70 (3d Cir. 1979). By contrast, “collateral estoppel” focuses on the issues and parties to an earlier litigation and binds those parties in a subsequent litigation of the same issues regardless of the level of review, if any.

Recognizing the difference between a decision having “precedential effect” and a decision giving rise to collateral estoppel, prior to the adoption of F.R.A.P. 32.1(a) in 2006, numerous federal appellate courts enacted local rules that precluded citation to non-precedential decisions except when cited, *inter alia*, for purposes of collateral estoppel. *See, e.g.*, 10th Cir. Rule 32.1(A) (“Unpublished decisions are not precedential, but they may be cited for their persuasive value. They may also be cited under the doctrines of law of the case, claim preclusion, and issue preclusion.”).

Simply put, “precedence” and “collateral estoppel” are distinct legal concepts and “precedence” has no bearing on this case.

## **5. The Secretary’s Appropriations Clause Argument**

The Secretary’s argument that applying collateral estoppel would violate the Appropriations Clause of the Constitution seems particularly off-base. *Opp.* at 22-23. In support of this argument, the Secretary cites several cases where *equitable estoppel* was at issue – *i.e.*, cases where, though no statute authorized payment or a statute barred payment, some conduct by the government (*e.g.*, erroneous advice) was alleged to estop the government from withholding payment. That was the situation in *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990) (wrong advice about earnings limits), *Monongahela Valley Hospital, Inc. v. Sullivan*, 945

F.2d 576 (3d Cir. 1991) (unclear information on depreciation rules), *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, 944 F.2d 756 (10th Cir. 1991) (wrong advice about billing), and *Genesis Health Ventures, Inc. v. Sebelius*, 79 F.Supp.2d 170 (D.D.C. 2011) (wrong advice about billing bases). Thus, the Secretary's quotes from these cases are taken out of context because they all concern equitable estoppel, not collateral estoppel.

By contrast, in the decisions on which Mrs. Oxenberg' and Mr. Lewis' assertions of collateral estoppel are based, the Secretary finally determined that the TTFT is a covered benefit in accordance with the laws passed by Congress. *See, e.g.*, Pistorino Dec. Ex. C (for Mrs. Oxenberg) at 9 (“[S]hall be covered pursuant to the provisions of Section 1682(a)(1) of the Social Security Act.”). Those decisions having become final. Thus, the Secretary is estopped to arrive at a different conclusion and deny their claims.

#### **E. The Secretary's Legal Claims Specific to Medicare Regarding Collateral Estoppel**

At least some of the Secretary's collateral estoppel arguments revolve around Medicare/the Medicare Act and those are addressed here.

##### **1. *De Novo* Review**

The Secretary contends that applying collateral estoppel would conflict with the requirement for the Council to review cases *de novo*. Opp. at 15 (citing 42 U.S.C. § 1395ff(d)(2)(B)). Again, this misapprehends fundamental principles.

“*De novo*” review merely means that the reviewing court conducts its review “independent, with no deference given to the trial court's conclusion.” *See, e.g., In re: Deitz*, 760 F.3d 1028, 1043 (9th Cir. 2014). Thus, the reviewing court decides matters in the same stead as the court or tribunal appealed from without any deference to the conclusions reached by the court or tribunal being reviewed.

Of course, such *de novo* review does not mean the reviewing court can proceed without regard to any legal principles or doctrines. Courts routinely apply collateral estoppel in matters subject to *de novo* consideration/review. Indeed, orders granting summary judgment based on collateral estoppel are subject to *de novo* appellate review, as is the application of collateral estoppel itself. *See, e.g., Prusky v. Reliastar Life Ins. Co.*, 532 F.3d 252, 265 (3d Cir. 2008) (applying *de novo* review to both issues). The Secretary’s position that collateral estoppel can never apply wherever there is *de novo* review is obviously incorrect.

In other words, there is no conflict between *de novo* review under 42 U.S.C. § 1395ff(d)(2)(B) and collateral estoppel.

**2. There is No Basis For The Secretary’s Assertion That He Did Not Have a Full and Fair Opportunity to Litigate**

The Secretary asserts that he did not have a full and fair opportunity, before the ALJs of his own department, to litigate the decisions forming the basis for collateral estoppel. In support of this position, the Secretary asserts a series of straw man arguments regarding Medicare proceedings below the ALJ level as well as what the Secretary’s regulations provide when an unrepresented beneficiary appears before an ALJ. *See Opp.* at 23, 26-27.

In this case, the decisions forming the basis for collateral estoppel are decisions of ALJs and not decisions of lower levels within the claim process (*e.g.*, redetermination and reconsideration). Thus, the Secretary’s comments in this regard (*Opp.* at 26) are irrelevant.<sup>11</sup> By contrast, clearly, the proceedings before the ALJ (and the Council) are the Secretary acting in a “judicial capacity” and, therefore, provide a proper basis for invoking collateral estoppel. *See Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (“When an

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<sup>11</sup> Though the proceedings below established the Secretary’s position with regard to coverage and that matter is what was litigated before the ALJ and Council.



administrative agency is acting in a judicial capacity ...”); *Utah Construction*, 384 U.S. at 422 (“When an administrative agency is acting in a judicial capacity and resolved ...”).

As to the Secretary’s assertions regarding his own regulations and the Secretary’s opportunity to litigate in the context of *unrepresented* beneficiaries, again, those comments are irrelevant. Opp. at 27. In each of the decisions forming the basis for collateral estoppel, Mrs. Oxenberg and Mr. Lewis were represented by counsel. *See, e.g.*, Pistorino Dec. Ex. A (for Mrs. Oxenberg) at 8 (“Debra Parrish, attorney, appeared on behalf of [Mrs. Oxenberg] ...”).

In such a case, the Secretary’s representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008, 405.1010. In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to the issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046. Like the beneficiary, if the Secretary is dissatisfied with the decision of the ALJ, the Secretary can appeal to the Council. *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ’s decision on so-called “own motion” review. *See* 42 C.F.R. § 405.1110.

Thus, the Secretary’s assertion that he did not have a full and fair opportunity to litigate (before the ALJs of his own department) or an opportunity for appellate review (Opp. at 27),

regardless of his chosen status before the ALJ, is without basis. The Secretary had a full and fair opportunity to litigate the issues when the agency was acting in a “judicial capacity.”

**3. Collateral Estoppel Would Not Be Contrary to Statutory Purpose, Frustrate Congressional Intent, or Impede Effective Functioning**

While the Secretary contends that applying collateral estoppel would conflict with a statutory purpose to the contrary or frustrate congressional intent, the Secretary never identifies any such statute or alleged intent. Opp. at 13. Indeed, there is no indication that Congress intended that persons suffering from lethal brain cancer be required to hire lawyers to embark on protracted, and repeated, legal battles simply to obtain the life-extending standard of care.

As far as impeding the effective functioning of the agency if collateral estoppel were applied, again, the Secretary has offered nothing. Based on publicly available data, the Secretary processes some one billion claims each year. *See* Pistorino Dec. Ex. M. As noted above, in FY 2019, those claims resulted in less than 5,200 beneficiary appeals at the ALJ level. This amounts to ALJ appeals in just 0.00052% of the claims.

Moreover, as indicated above, presumably only a fraction of the 5,200 beneficiary appeals are by represented parties. Indeed, at least some portion of the 5,200 beneficiary appeals are the result of the Secretary’s own doing. For example, as a result of the Secretary’s repeated litigation in this case, simply deciding whether Mrs. Oxenberg and Mr. Lewis can receive the life-extending TTFT treatment has resulted in six (6) ALJ appeals and decisions, so far. Were collateral estoppel properly applied, at least some number of ALJ appeals might be avoided and/or the burden of deciding the same issues in successive appeals involving the same parties would be minimized.

Further, of course, the Secretary would be still be in a position to decide which cases warranted his attention while relying on the fact that the beneficiary bears the burden of proof in all the other cases. Applying collateral estoppel to this small fraction of cases could hardly impede

the functioning of the agency. Because collateral estoppel could also be applied against beneficiaries, it could actually reduce the government's burden of repeated adjudication.

The Secretary's citation to *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012) (Opp. at 15) is inapposite because, again, that case involved only an "arbitrary and capricious" review across multiple cases (and apparently different plaintiffs) and not collateral estoppel.

#### **4. Alleged Interference With Discretion to Implement the Medicare Statute**

On pages 16-20, the Secretary presents a broad argument that his actions are immune from the opinions of the Supreme Court (*Astoria* and *Utah Construction*) or any legal principles because that would interfere with the Secretary's "discretion" to implement the Medicare Act. In support of this claim, the Secretary cites a mishmash of cases, involving disparate facts and irrelevant issues, and quotes various passages from such cases out of context.

Under *Astoria* and *Utah Construction*, collateral estoppel only applies when a Department or agency is acting in a "judicial capacity." Thus, the Secretary's citations to, and quotes from, *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030 (D.C. Cir. 2008) and *Comcast Corp. v. F.C.C.*, 526 F.3d 763 (D.C. Cir. 2008), are not relevant because they involve only non-judicial proceedings/statements by agencies. See *Devon*, 551 F.2d at 1040 (Royalty Policy Board statements); *Comcast*, 526 F.2d at 769 (FCC Media Bureau waivers).

Along these same lines, the Secretary cites and quotes from six cases concerning the Provider Reimbursement Review Board (PRRB).<sup>12</sup> The PRRB is not composed of ALJs. Instead,

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<sup>12</sup> *Community Care Foundation v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (non-final decision of PRRB, "a five-member panel of experts"); *Abraham Lincoln Memorial Hospital v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408 (7th Cir. 1987) ("[T]he Secretary's minions have taken a different view ..."); *County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008).

the PRRB is a five-member panel of “persons knowledgeable in the field of healthcare reimbursement” (42 C.F.R. § 405.1817) charged with reviewing accounting decisions of contractors regarding reimbursements to providers. In the words of the Seventh Circuit, the PRRB is comprised of “minions” within the Department. *Homemakers N. Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987). Thus, again, the PRRB is not an instance of the Department acting in a “judicial capacity” and these cases are irrelevant.

As to the Secretary’s allegation that applying collateral estoppel would interfere with his discretion to decide matters by promulgating rules or by individual adjudication (Opp. at 16), there is nothing to that. Where the Secretary has elected to proceed by individual adjudication, applying collateral estoppel would not interfere with that choice. Instead, it would only mean that collateral estoppel may, or may not, apply as to that particular plaintiff in that individual adjudication.

For example, the next time that Mrs. Oxenberg submits a claim for coverage of her TTFT device, that matter will be individually adjudicated. Based on her earlier favorable decisions, Mrs. Oxenberg will assert that (absent changed circumstances) the Secretary is collaterally estopped from denying that TTFT is a covered Medicare benefit for her/is “medically reasonable and necessary.” Indeed, absent changed circumstances, that will be the case in all future claims by Mrs. Oxenberg. Thus, just as in *Moser*, individual adjudication using collateral estoppel does not interfere with the Secretary’s discretion to choose the manner of resolving claims.

The Secretary’s citation to *International Rehab Science Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (Opp. at 19) is inapposite because, again, that case involved only an “arbitrary and capricious” review across multiple cases and not collateral estoppel. Likewise inapposite is the Secretary’s out of context citation to, and quotation from, *Freeman v. U.S. Department of Interior*, 37 F.Supp.3d 313, 344-45 (D.D.C. 2014). Opp. at 19. The court’ comments that the

Secretary references from that decision were in the context of a plaintiff that argued that prior ALJ decisions to which it was not a party “bound” the Department in a non-mutual, collateral estoppel sense. Citing *Mendoza*, the court there properly rejected that assertion. *Id.* at 346 (“Under these circumstances, the general rule amply applies and no non-mutual preclusive effect is warranted for the ALJ rulings in *Aloisi* and *Story*.”). As already shown, such reasoning is inapplicable where mutuality exists.

**5. Because the Lewis’ Decision is Final, it Supports Collateral Estoppel Against Still Pending Claims**

In a single sentence, the Secretary argues that collateral estoppel cannot apply in Mr. Lewis’ case because the favorable decision giving rise to collateral estoppel was issued by the ALJ after the unfavorable decision being appealed in this case. *Opp.* at 11. That is wrong as a matter of law.

As detailed in Plaintiffs’ opening papers, when parallel/concurrent litigation is at issue, whichever decision reaches finality first may give rise to collateral estoppel in another, still-pending and non-final case. *See* Opening Br. at 2. Here, ALJ Hynum’s decision reached finality first and, thus, gives rise to collateral estoppel against ALJ Levine’s still non-final decision.

**6. The Secretary’s Assertion that Applying Collateral Estoppel Would Be Unfair**

The Secretary asserts that applying collateral estoppel to the final decisions of the Secretary when he is acting in a “judicial capacity” would be unfair. *Opp.* at 27-31. In support of this argument, the Secretary relies on the false “400,000 ALJ appeals filed each year” claim. *Opp.* at 29. The rest of the Secretary’s argument fares no better.

The Secretary asserts that he had no reason to believe that ALJ decisions could have preclusive effect in future claims because that is contrary to “Medicare statutes, regulations, Supreme Court precedent, and a number of circuit-level decisions.” *Opp.* at 29. As detailed above,

that is simply not the case where the preclusive effect is limited to the mutual collateral estoppel context. Indeed, the Secretary has failed to identify any such statutes, regulations, or precedent that holds to the contrary. What the Supreme Court has said is that if a department or agency is acting in a “judicial capacity” then mutual collateral estoppel may apply against the government as it does against any private party. *See Astoria, Utah Construction, Mendoza*.

Without any basis, the Secretary asserts that applying collateral estoppel would be unfair because collateral estoppel would only apply against the Secretary and not against beneficiaries. Opp. at 31. That is simply untrue. At a minimum, if a represented beneficiary appealed a denial to an ALJ and a negative decision from the ALJ became final, then the beneficiary could also be collaterally estopped in future claims (absent changed circumstances). Indeed, in the non-Medicare context, the government has asserted collateral estoppel based on prior final ALJ decisions. *See, e.g., Cannon v. U.S.*, 2019 WL 5550065 at \*4-5 (S.D. Cal. Oct. 28, 2019) (plaintiff collaterally estopped by ALJ decision that became final while district court case was pending). Thus, mutual collateral estoppel is no more, or less, applicable to the United States than it is to private parties.

Clearly, it is fair to apply collateral estoppel against the Secretary when the Secretary had the full-panoply of rights as a litigant, has imposed those costs on Mrs. Oxenberg and Mr. Lewis, and, having lost, did not appeal and allowed the decisions adverse to himself to become final. Moreover, because only mutual collateral estoppel is at issue, there is no bar to different ALJs (or even the same ALJ) arriving at different conclusions on TTFT claims brought by beneficiaries other than Mrs. Oxenberg and Mr. Lewis.

Unquestionably, a failure to apply collateral estoppel would be unfair to Mrs. Oxenberg and Mr. Lewis. While suffering from deadly brain cancer, Mrs. Oxenberg and Mr. Lewis have

been forced to bear the costs, delays, and uncertainty of repeated litigation of the same coverage issues. To nonsensically sentence Mrs. Oxenberg and Mr. Lewis to bear these burdens time and again would clearly be unfair.

Moreover, not applying collateral estoppel could lead to a massive increase in litigation and be unfair to the Courts as well. Simply as an example, every GBM patient could result in as many as four district court litigations each year because: 1) the device is rented on a monthly basis - meaning that there will be continuing periodic claims for Medicare coverage (typically every three months); and 2) beneficiaries are required to bring suit in district court within 60 days of each final decision from the Secretary (*see* 42 U.S.C. § 405(g)). Thus, Mrs. Oxenberg and Mr. Lewis alone could result in eight (8) additional cases on this Court's docket each year.

**F. The Secretary's Erroneous Assertion Regarding the Causes of Action in this Case**

On pages 3, fn. 3, and 11, and in his proposed Order, the Secretary asserts that if Plaintiffs' motion to apply collateral estoppel is denied, then Mrs. Oxenberg' and Mr. Lewis' claims should be dismissed. Respectfully, that reflects a serious misunderstanding of the procedural posture of this case.

As detailed in the Complaint, both Ms. Oxenberg have a number of causes of action alleging that the Secretary's denial of their claims fails to comply with the law under various sections of the APA. Simply as an example, Plaintiffs allege that the decisions should be reversed because they are "arbitrary and capricious." *See* Complaint, Count III. In support of those Causes of Action, Plaintiffs assert that the Secretary is collaterally estopped from denying coverage. However, should the Court decide against Plaintiffs on this ground, it would merely mean that the Secretary was not estopped. Plaintiffs' Causes of Action would remain to be resolved with each side bearing its burdens of proof.

Both parties have merely moved for summary judgment as to whether collateral estoppel applies without addressing the substantive merits of the underlying claims. In Mrs. Oxenberg' and Mr. Lewis' case, the very purpose of asserting collateral estoppel is so that they do not have to bear the burden of relitigating the issues, avoiding waste of judicial resources, and avoiding inconsistent results. If Mrs. Oxenberg and Mr. Lewis motion for summary judgment is denied, the merits of the underlying claims will remain to be addressed.

## II. CONCLUSION

The Secretary's cross-motion for summary judgment should be denied and Mrs. Oxenberg' and Mr. Lewis' motion granted. The Secretary should be collaterally estopped from denying that TTFT is "medically reasonable and necessary" and a covered Medicare benefit for Mrs. Oxenberg and Mr. Lewis. The decisions at issue in this case should be reversed and coverage of Ms. Oxenberg and Mr. Lewis' claims ordered.

Dated: May 4, 2020

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, hereby certify that on this 4th day of May, 2020, I electronically filed the foregoing Plaintiffs' Reply in Further Support of Motion for Summary Judgment and Opposition to Cross-Motion for Summary Judgment and supporting papers with the Clerk of Court using the CM/ECF system as follows:

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